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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/562,524	09/13/2006	Wolfgang H. Dillmann	UCSD1620-1	8043

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EXAMINER	
SCHULTZ, JAMES	
ART UNIT	**PAPER NUMBER**
1633	

MAIL DATE	DELIVERY MODE
03/04/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/562,524	DILLMANN ET AL.	
	Examiner	Art Unit	
	JD SCHULTZ	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 December 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 3-29* is/are pending in the application.

4a) Of the above claim(s) *15-26* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-14 and 27-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *27 December 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group I, claims 1, 3-14 and 27-29 in the reply filed on 12/17/2009 is acknowledged.

Claims 15-26 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 12/17/2009.

Information Disclosure Statement

The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Oath/Declaration

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:
Non-initialed and/or non-dated alterations have been made to the oath or declaration. See 37 CFR 1.52(c).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 3-14, and 27-29 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claimed invention is not considered to be enabled, since the combination of the prior art and the teachings of the instant specification are not considered to support the breadth of the instant claims. There is sufficient evidence in the prior art to support the finding that the state of the art is sufficiently unpredictable such that in order to practice the instant invention, one of skill would necessarily have to engage in undue trial and error experimentation.

The factors listed below have been considered in the analysis of enablement:

(A) The breadth of the claims;
(B) The nature of the invention;
(C) The state of the prior art;
(D) The level of one of ordinary skill;
(E) The level of predictability in the art;
(F) The amount of direction provided by the inventor;
(G) The existence of working examples; and
(H) The quantity of experimentation needed to make or use the invention based on the content of the disclosure.

The claims are broadly drawn to methods of increasing contractile function in the heart in any subject, comprising delivering a viral vector which provides for the expression of sorcin. The state of the prior art relates to gene therapy, which is considered to be a highly unpredictable field. There have been sporadic reports of success and no accepted treatments that employ gene therapy despite many years and many billions of dollars worth of research effort. There are two

generally accepted challenges that face the field; the first is achieving delivery to the appropriate target tissue and expression of the gene contained therein, and the second relates to whether replacing the designated gene is sufficient to result in treatment of the disease. It is acknowledged that under narrow circumstances of delivery, such as direct injection of viral vectors into the target tissue as exemplified by applicants in the instant specification, expression of a delivered gene may occur. Whether or not that expression rises to the level of accomplishing any treatment is at issue. This is not to assert that there are no successes reported in the field; indeed, Kizana et al. (Heart, Lung and Circulation 2007;16:180–184) report "[e]xciting developments in gene transfer technology and important insights into the molecular basis of these common diseases have placed them within reach of gene-based therapy." However, Kizana et al. go on to indicate that treatment is a ways off: "One emerging theme from these trials is the inadequacy of the vectors employed. Additionally, vector-associated serious adverse reactions resulted in widespread publicity and dealt a major setback to the field. Herein lies the warning contained in the Sirens' analogy, that is, to resist the temptation to premature human application."

Currently, the preponderance of evidence in the prior of the art relating to delivery and expression of genes to treat heart conditions is not considered to be sufficient in and of itself to support a finding of non-enablement. However, when combined with evidence from the prior art that the gene (in this case sorcin) may not be sufficient or even adequate to achieve the claimed function of increasing heart contractility, these two factors are considered sufficient to support a finding of unpredictability. Seidler et al. (Circ Res. 2003;93:132-139.) indicate that adenoviral-delivered sorcin actually reduced fractional shortening of cardiac muscle cells in vitro. This

result stands in direct contrast to that exemplified by applicants instantly in the specification. This contrast requires resolution for the instant claims to be considered enabled over their full scope. Applicants are invited to furnish evidence or reasoning that would suggest why the findings of Seidler do not apply to the instant invention. While it is acknowledged that the teachings of Seidler are carried out in vitro, and that the instant exemplification is directly delivered in vivo, this does not necessarily explain away such apparently opposite findings. This is particularly true in the case of claim 9, which requires prevention of heart failure.

In view of the art, the quantity of experimentation required to practice the invention as claimed is considered to be undue, and since the various complications in regards to achieving treatment via vector mediated delivery of sorcin as discussed above are considered unresolved, one of skill in the art would have been unable to practice the invention without engaging in undue trial and error experimentation as presented in the specification over the scope claimed.

Conclusion

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to J. Douglas Schultz, Ph.D. whose telephone number is 571-272-0763. The examiner can normally be reached on 8:00-4:30 M-F.
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached at 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

/JD SCHULTZ/
Primary Examiner, Art Unit 1633